



UNITED STATES PATENT AND TRADEMARK OFFICE

m'

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/695,022	10/23/2000	Steven Z. Wu	M-8873 US	3060

7590

11/21/2003

Cameron Kerrigan
SQUIRE, SANDERS & DEMPSEY L.L.P.
One Maritime Plaza,
Suite 300
San Francisco, CA 94111-3492

EXAMINER

PREBILIC, PAUL B

ART UNIT	PAPER NUMBER
----------	--------------

3738

16

DATE MAILED: 11/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/695,022

Applicant(s)

WU ET AL.

Examiner

Paul B. Prebilic

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4,8-11,21-25,27 and 28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,4,8-11,21-25,27 and 28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Claim Objections

Claims 1 and 23 are objected to because of the following informalities:

On line 3 of claim 1, the language "a groove-disposed" is grammatically awkward and not understood. It appears that the hyphen was inadvertently placed between the two words when the editorial marks were being made.

Claim 23 is grammatically awkward because the language "an adhesive bonding said filament in said groove" is not clear. In particular, it is not clear whether this limitation is a structural or a process of making limitation. Therefore, the Examiner will interpret this language as if it were written as "adhesively bonding said filament in said groove."

Appropriate correction is required.

Claim Rejections Based Upon Prior Art

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 3738

Claims 1, 3, 4, 8, 9, 11, 21, 22, 24, 25, 27 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Brown et al (WO 98/23228), or alternatively, under 35 USC 103(a) as being unpatentable over Brown et al (WO 98/23228) alone. Brown et al anticipates the claim language where the filament portions are the active agents in carriers (23,25) of Brown and they are "string filaments" to the extent this claim language can be given patentable weight; see especially Figures 2 and 9 and pages 9 and 16. The active agent with carrier (23,25) is considered to be a string filament to the extent required by the present claim language because it fulfils the second definition given for the term "string" by the Random House College Dictionary ((c) 1972) on page 1301. "String" is defined therein as:

- "1. a slender cord or thick thread for binding or tying; line*
- 2. Something resembling a cord or thread."*

Since elements (23) and (25) of Brown resemble a cord or thread in that it resembles a slender cord or thick thread, the claim language requiring a "string filament" is fully met in this regard.

Alternatively, one may not consider the active agent with carrier (23, 25) to be a string filament as claimed. However, at the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to make element(s) (23, 25) into tensile-force capable structure because Applicants have not disclosed that making therapeutic substance release device into tensile-force capable structure provides some advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicants' invention to perform equally well at releasing therapeutic substances because both the

Art Unit: 3738

string filament material and the carrier(s) (23,25) have the common function of releasing therapeutic substances. Therefore, it would have been an obvious matter of design choice to modify Brown to obtain the invention as specified in the claims.

With regard to claims 3 and 4 specifically, by measuring the features of Figure 9 and since the depth of a groove in Brown's Figure 9 is about 16 mm and the diameter is about 43 mm, the groove of Brown is about 37% of the diameter. For this reason, the claim limitations are fully met in this regard.

With regard to claim 6 specifically, it is noted that the limitation of exposing the body to a laser is a method limitation. For this reason, it is not afforded much patentable weight in that it is product-by-process limitation; see MPEP 2113, which is incorporated herein by reference there. In particular, if the product is not considered to be identical, it is considered to be at least substantially identical to the extent that it is clearly obvious thereover.

With regard to claim 8, it is noted that collagen, one of the agents of carriers, is a polymer of amino acids as are all proteins. For this reason, the claim language is fully met. Furthermore, the delivery matrix of Brown can contain other polymers; see page 13, lines 3-14.

With regard to claim 11, the barrier as claimed is present by the top end of the groove, which converges into a slit. Therefore, the present claim is at least obvious in view of Brown et al, which clearly suggests it.

With regard to claim 22, Applicant is directed to see elements (114) of Figure 18.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brown et al (WO 98/23228) in view of Fischell et al (US 5,722,984). Brown et al at least renders obvious the claim language as set forth above. Brown fails to teach the use of a radioactive isotope as claimed. Fischell et al, however, teaches that it was known to use radioactive isotopes in stent devices in order to reduce cell proliferation and restenosis; see especially the abstract. Hence, it is the Examiner's position that it would have been obvious to use a radioactive isotope along with or in place of the active agents of Brown et al in order to reduce cell proliferation and restenosis as taught by Fischell et al.

Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brown et al (WO 98/23228) alone. Brown at least renders obvious the claim language as set forth in the Section 102 rejection above, but Brown fails to disclose the use of an adhesive with the filaments as claimed. However, since Brown discloses using other elements therewith (see page 13) and since the use of adhesive provides no stated advantage or unexpected/unobvious result, it is the Examiner's position that it would have been prima facie obvious to use an adhesive with or on the drug depot of Brown in order to better secure it to the stent body.

Alternatively, with regard to claim 23 specifically, it is noted that the limitation of adhesively bonding of the filament in the groove is a method limitation that does not necessarily require an adhesive; in other words, it only requires an adhesive functionality. For this reason, it is not afforded much patentable weight in that it is product-by-process limitation; see MPEP 2113, which is incorporated herein by

reference there. In particular, if the product is not considered to be identical, it is considered to be at least substantially identical to the extent that it is clearly obvious thereover.

Response to Arguments

Applicant's arguments filed September 12, 2003 have been fully considered but they are not considered persuasive.

With regard to the 35 USC 112, first and second paragraph rejection traversals of the amendment, the Examiner has withdrawn these grounds of rejection because the term "string-like" was removed from the claims.

Applicants argue that Brown fails to disclose a string filament. However, the Examiner asserts the term "string" encompasses the structure as set forth in Brown's disclosure because it fulfils the second definition given for the term "string" by the Random House College Dictionary ((c) 1972) on page 1301. "String" is defined therein as:

- "1. a slender cord or thick thread for binding or tying; line.*
- 2. Something resembling a cord or thread."*

Since element (23) or (25) of Brown resembles a cord or thread in that it resembles a slender cord or thick thread, the claim language requiring a "string filament" is fully met in this regard.

Applicants argue that once the coating solvent is evaporated, the resultant structure does not have a string filament structure as required by the claims. However, the Examiner asserts that there is no evidence that the end product is substantially different from that shown in the drawings of Brown. Rather, the Examiner asserts that

the end product of Brown is shown in the drawings. Furthermore, Brown uses non-biodegradable and low soluble materials for the purpose of maintaining the delivery matrix in the groove for an extended period of time; see page 13, lines 3-14 of Brown. For these reasons, the arguments are considered unpersuasive.

In response to the Applicants assertion that a secondary reference is needed in the Section 103 rejection, the Examiner asserts that this is not true. Single reference obviousness rejections are well established as acceptable means of showing unpatentability; see MPEP 2113 for example; the obvious design choice rejection is another example and was used in this particular case. For these reasons, the traversal is considered unpersuasive.

Furthermore, contrary to Applicants speculation, it was never the intention of the Examiner to take "official notice" in this rejection. For this reason, the criteria of MPEP 2144.03 are not applicable.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

Art Unit: 3738

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Prebilic whose telephone number is (703) 308-2905. The examiner can normally be reached on Monday-Thursday from 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for this Technology Center is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 3700 receptionist whose telephone number is (703) 308-0858.



Paul Prebilic
Primary Examiner
Art Unit 3738